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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/359,326	07/20/99	REITER	R 30435.54US14

HM12/0712
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EXAMINER	
HELMS,L	
ART UNIT	**PAPER NUMBER**
1642	7

DATE MAILED: 07/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/359,326	Applicant(s) Reiter et al
	Examiner Larry R. Helms Ph.D.	Group Art Unit 1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *NONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-68* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-68* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

It is pointed out that there are two claim 12's in the application. As such the second claim 12 will be renumbered as claim 13 and all subsequent claims numbered in sequence from claim 13 (i.e. original claim 13 will be 14 and original claim 14 will be 15, etc.). The dependancy has also been changed.

2. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented some of the instant claims in improper format, for example claims 18-27, 34-36, 42-51, and 58-61. The claims are improperly joined as the various groups indicated below appear to encompass distinct targets of tumor cells to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespectively of the improper format of the claims, because these are not proper species.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 8-11, drawn to a monoclonal antibody and hybridoma producing such wherein the antibody binds to the extracellular domain of PSCA, classified in class 530, subclass 388.85.

II. Claim 7, drawn to a transgenic animal producing an antibody, classified in class 800, subclass 6.

III. Claims 12-17, drawn to an immunoconjugate, classified in class 530, subclass 391.7.

IV. Claims 18-27, 34-36 in part, and 28-29, drawn to a method of inhibiting the growth of prostate carcinoma cells and metastasis of human prostate carcinoma tumor cells expressing PSCA comprising administering an antibody which specifically binds to the extracellular domain of PSCA, classified in class 424, subclass 183.1. If Group III is elected claims 18-27 and 34-36 will be examined to the extent that the tumor cells are prostate carcinoma cells and metastasis of human prostate carcinoma tumor cells.

V. Claims 18-27, 34-36 in part, and 30-31, drawn to a method of inhibiting the growth of human bladder carcinoma cells and metastasis of human bladder carcinoma tumor cells expressing PSCA comprising administering an antibody which specifically binds to the extracellular domain of PSCA, classified in class

424, subclass 183.1. If Group IV is elected claims 18-27 and 34-36 will be examined to the extent that the tumor cells are human bladder carcinoma cells and metastasis of human bladder carcinoma tumor cells.

VI.. Claims 18-27, 34-36 in part, and 32-33, drawn to a method of inhibiting the growth of human pancreatic carcinoma cells and metastasis of human pancreatic carcinoma tumor cells expressing PSCA comprising administering an antibody which specifically binds to the extracellular domain of PSCA, classified in class 424, subclass 183.1. If Group V is elected claims 18-27 and 34-36 will be examined to the extent that the tumor cells are human pancreatic carcinoma cells and metastasis of human pancreatic carcinoma tumor cells.

VII. Claims 37-41, and 65, drawn to a method of inhibiting the growth of tumor cells expressing PSCA comprising administering a combination of monoclonal antibodies which specifically binds to the PSCA antigen, classified in class 424, subclass 156.1.

VIII. Claims 42-51 and 58-61 in part, and claims 52-53 and 62, drawn to a method of treating a patient susceptible to or having a cancer comprising administering an antibody which binds to the extracellular domain of PSCA, wherein the tumor cells are human prostate carcinoma and metastasis of a human prostate carcinoma, classified in class 424, subclass 183.1. If Group VII is elected claims 42-51 and

58-61 will be examined to the extent that the tumor cells are human prostate carcinoma and metastasis of a human prostate carcinoma.

IX. Claims 42-51 and 58-61 in part, and claims 54-55 and 63, drawn to a method of treating a patient susceptible to or having a cancer comprising administering an antibody which binds to the extracellular domain of PSCA, wherein the tumor cells are human bladder carcinoma and metastasis of a human bladder carcinoma, classified in class 424, subclass 183.1. If Group VIII is elected claims 42-51 and 58-61 will be examined to the extent that the tumor cells are human bladder carcinoma and metastasis of a human bladder carcinoma.

X Claims 42-51 and 58-61 in part, and claims 56-57 and 64, drawn to a method of treating a patient susceptible to or having a cancer comprising administering an antibody which binds to the extracellular domain of PSCA, wherein the tumor cells are human pancreatic carcinoma and metastasis of a human pancreatic carcinoma, classified in class 424, subclass 183.1. If Group IX is elected claims 42-51 and 58-61 will be examined to the extent that the tumor cells are human pancreatic carcinoma and metastasis of a human pancreatic carcinoma.

XI. Claims 66-68, drawn to a method for selectively inhibiting the growth of a cell comprising reacting an immunoconjugate or immunotoxin to the cell, classified in class 424, subclass 183.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibody of Group I, the immunoconjugate of Group III, and the transgenic animal of Group II are structurally, physically, and chemically different from each other. The antibody is raised by immunization, the immunoconjugate is made by recombinant or synthetic chemistry and the transgenic animal is made by recombinant DNA techniques. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-III are patentably distinct.

The methods of Inventions IV-XI differ in the method objectives, parameters, targets, and in the reagents used. Invention III recites a method of inhibiting the growth of human prostate carcinoma tumor cells expressing PSCA comprising administering an antibody which specifically binds to the extracellular domain of PSCA; Invention IV recites a method of inhibiting the growth of human bladder carcinoma tumor cells expressing PSCA comprising administering an antibody which specifically binds to the extracellular domain of PSCA; Invention V recites a method of inhibiting the growth of human pancreatic carcinoma tumor cells expressing PSCA comprising administering an antibody which specifically binds to the extracellular domain of PSCA; Invention VI recites a method of inhibiting the growth of tumor cells expressing PSCA comprising administering a combination of monoclonal antibodies which specifically binds to the PSCA antigen; Invention VII recite a method of treating a patient

susceptible to or having a cancer comprising administering an antibody which binds to the extracellular domain of PSCA, wherein the tumor cell is a human prostate carcinoma cell; Invention VIII recite a method of treating a patient susceptible to or having a cancer comprising administering an antibody which binds to the extracellular domain of PSCA, wherein the tumor cell is a human bladder carcinoma cell; Invention IX recite a method of treating a patient susceptible to or having a cancer comprising administering an antibody which binds to the extracellular domain of PSCA, wherein the tumor cell is a human pancreatic carcinoma cell and Invention X recites a method for selectively inhibiting the growth of a cell comprising reacting an immunoconjugate or immunotoxin to the cell. In addition, the tumor cells of prostate, bladder, and pancreatic are all distinct cells with the cancer arising in distinct areas of the organs. Adenocarcinoma of the prostate usually arises within the peripheral zone and most often posteriorly in that zone. A less common site of origin is the anteromedial prostate. Bladder cancer can be present as a low grade papillary lesion, as an in situ lesion which can occupy large areas of the mucosal surface, or as an infiltrative cancer that rapidly extends through the bladder wall. While pancreatic cancer arise in the head of the pancreas, eventually causing bile duct obstruction, pain, and clinical jaundice. Thus, prostate, bladder, and pancreatic cancer are all distinct. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions IV-XI are separate and distinct in having different method objectives, parameters, targets, and in the reagents used and are patentably distinct.

Inventions I and (IV-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in any of the materially different methods of Groups IV-X.

Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of Group XI can be practiced with a materially different product such as chemotherapy in addition to the immunoconjugates of Group III.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Sequence Requirements

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures and the marked up copy of the Raw Sequence Listing Error Report.

7. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

8. APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3559. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

JULIE BURKE
PRIMARY EXAMINER

Application No.: 09/359326

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE